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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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WRITTEN OPINION (PCT Rule 66)

Date of mailing
(day/month/year)

28.05.2004

Applicant's or agent's file reference
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REPLY DUE

within 3 month(s)
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International application No.
PCT/US 03/36488

International filing date (day/month/year)
17.11.2003

Priority date (day/month/year)
15.11.2002

International Patent Classification (IPC) or both national classification and IPC
A61B18/14

DOCKETED

Applicant
C.R. BARD, INC. ET AL.

JUN 3 2004

Confirmation

Initials

Docketing

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 15.03.2005

Name and mailing address of the international preliminary examining authority:



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JC20 Rec'd PCT/PTO 1 6 MAY 2005

WRITTEN OPINION

International application No. PCT/US 03/36488

I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-4, 6-13 as originally filed
 5 received on 15.03.2004 with letter of 15.03.2004

Claims, Numbers

1-35 as originally filed

Drawings, Sheets

1/4, 3/4, 4/4 as originally filed
 2/4 received on 15.03.2004 with letter of 15.03.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 16-35

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 16-35 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1,10-12,15
Inventive step (IS)	Claims	2,6,8,9,13,14
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The various definitions of the subject-matter given in the plurality of independent claims, each reciting a different combination of limitations expressed at different levels of generalizations and largely repetitive, are such that the claims as a whole are not clear and concise. The requirements of Article 6 PCT, therefore, are not met.

Consequently, the different combinations of features recited in the plurality of independent claims do not allow to correctly identify "the claimed invention" on which an opinion in the sense of Article 33.1 PCT should be based.

Therefore, this presentation of a number of independent claims makes it difficult, if at all possible, to determine the matter for which protection is sought and places an undue burden to others seeking to establish the extent of monopoly requested.

For this reason a full substantive preliminary examination cannot be carried out until the claims meet Article 6 PCT.

In the following an opinion is given on the first independent claim and its dependent claims.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Cited documents

Reference is made to the following documents:

- D1: US-B1-6 287 306 (PENDAKANTI RAJESH ET AL) 11 September 2001 (2001-09-11)
- D2: US-A-6 030 382 (FLEISCHMAN SIDNEY D ET AL) 29 February 2000 (2000-02-29)
- D3: US 2002/072744 A1 (BOWMAN BRETT ET AL) 13 June 2002 (2002-06-13)
- D4: EP-A-1 151 726 (BIOSENSE WEBSTER INC) 7 November 2001 (2001-11-07)
- D5: US-B1-6 456 863 (FLEISCHMAN SIDNEY D ET AL) 24 September 2002 (2002-09-24)

V.1 Novelty

The present application does not meet the requirements of Article 33(2) PCT, because the subject matter of claim 1 is not new.

The document D1 discloses (the references in parentheses applying to this document):

an apparatus for ablating tissue comprising:

a shaft; and

a tissue ablating electrode (34) mounted on the shaft, the electrode comprising a first end portion (35) and a middle portion, wherein the first end portion is configured differently than the middle portion such that, when the electrode is energized, the ratio of a first density of ablation energy that is emitted in a vicinity of the first end portion to a second density of ablation energy that is emitted in a vicinity of the middle portion is lower than the ratio would be if the first end portion were configured the same as the middle portion (cf. col.4, l.60-64; fig.4)

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

V.2 Dependent claims 2-15

Dependent claims 2,6,8-15 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty and/or inventive step, the reasons being as follows:

claim 2: coiled electrodes are known from D2 (cf. col.4, l.35-49; fig. 2), the skilled person would therefore also consider the implementation of the teaching of D1 in a coiled electrode catheter described in D2;

claim 6: interleaved spirals are known from D3 (cf. par 45; fig. 8) and therefore the subject matter of claim 6 is not inventive;

claims 8,9: a partially covered end surface of an electrode is disclosed in D4 (cf. par.19) for the purpose of prevention of edge effects. Therefore claim 8 is not inventive;

claims 10-12: the subject matter of these claims is disclosed in D1;

claim 13,14: partially covered end portions and upper surfaces of end portions substantially flush with the shaft surface are known from D5 (cf. fig .18) and therefore not inventive;

claim 15: the features of this claim are already disclosed in D1;

The subject matter of dependent claims 3-5 and 7 are neither known from nor rendered obvious

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/US03/36488

by the prior art cited.